14 SEP 2005 **FORM PTO-1390** US DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE ATTORNEY'S DOCKET NUMBER (REV. 01-2003) 124055 TRANSMITTAL LETTER TO THE UNITED STATES U.S. APPLICATION NO. (If known, see 37 CFR 1.5) DESIGNATED/ELECTED OFFICE (DO/EO/US) 10/536.459 CONCERNING A FILING UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/JP2003/15005 November 25, 2003 November 25, 2002 TITLE OF INVENTION AGENT FOR TREATING RESPIRATORY DISEASES CONTAINING 4-HYDROXYPIPERIDINE DERIVATIVE AS ACTIVE **INGREDIENT** APPLICANTS FOR DO/EO/US Yasushige AKADA; Kazuyuki MATSUURA Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 2. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include 3. items (5), (6), (9) and (21) indicated below. 4. \Box The US has been elected (Article 31). 5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2)) b.

has been communicated by the International Bureau. 6. An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)) b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4). The International Application was filed in English. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) 7. b. have been communicated by the International Bureau. c. In have not been made; however, the time limit for making such amendments has NOT expired. d.
 have not been made and will not be made. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 8. 9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. A preliminary amendment. 13.

A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.

A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

A second copy of the published international application under 35 U.S.C. 154(d)(4).

page 1 of 2

14.

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19. 20. An Application Data Sheet under 37 CFR 1.76.

A power of attorney and/or change of address letter.

A substitute specification.

Other items or information:

U.S. APPLICATION I 10/536,459	APPLICATION NO. (If known, see 37 C.F.R. 1.5) INTERNATIONAL APPLICATION NO. PCT/JP2003/15005				ATTORNEY'S DOCKET NUMBER 124055						
21. The following fees are submitted:					CALCULATIONS	PTO USE ONLY					
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must	be filed and g	granted to restore	e the application to p	ending status.		., .,					
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OLIFF & BERRIDGE, PLC Customer Number: 25944 NAME: James/A. Oliff											
					ON NUMBER: 27,0	75					
Date <u>Septe</u>	mber 14, 200	e O. Collier ON NUMBER: 53,839									

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In rethe Application of

Yasushige AKADA et al.

Application No.: 10/536,459 Group Art Unit: 1623

Filed: May 25, 2005 Docket No.: 124055

For: AGENT FOR TREATING RESPIRATORY DISEASES CONTAINING 4-

HYDROXYPIPERIDINE DERIVATIVE AS ACTIVE INGREDIENT

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- 1. This Information Disclosure Statement is being filed (a) within three months of the U.S. filing date of this non-CPA application, OR (b) before the mailing date of a first Office Action on the merits in the present application. No certification or fee is required.
- 2. Relevance of the references is discussed in the present specification.

Respectfully submitted,

James A. Oliff

Registration No. 27,075

Jesse O. Collier

Registration No. 53,839

JAO:JOC/nxy

Date: September 14, 2005

OLIFF & BERRIDGE, PLC P.O. Box 19928 Alexandria, Virginia 22320 Telephone: (703) 836-6400 DEPOSIT ACCOUNT USE
AUTHORIZATION
Please grant any extension
necessary for entry;
Charge any fee due to our
Deposit Account No. 15-0461

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Form PTO-1449 US Dept. of Commerce (REV. 8-83) PATENT & TRADEMARK OFFICE					ATTY DOCKET NO. 124055			APPLICATION NO. 10/536,459				
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(Use several sheets if necessary)				APPLICANTS Yasushige AKADA et al.								
					FILING DATE May 25, 2005			GROUP 1623				
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	L	OTHER DOCUMENTS (Inc	21									
	4.	Bruno S. HUEGI et al.; "Synthesis and Pharmacological Studies of 4,4-Disubstituted Piperidines: A New Class of										
		Compoundswith Potent Analgesic Properties"; J. Med. Chem; 1983; Vol 26; pp. 42-50.										
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Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Date: September 14, 2005

Examiner: